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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/875,349	06/05/2001	John C. Hiserodt	IRVN001DIV	8040

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EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/875,349	HISERODT ET AL.	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *03 November 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): 35 USC 112, 1st and 2nd paragraph; 102(a)-- Tuck et al .

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See attached* .

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: *34,38,39,41-48,50,51,63-66,71,73,75-77,80 and 81 (see paragraph 2 attachment)*.

Claim(s) rejected: *31-33,35-37,40,49,52,62,64,67-70,72,74,78 and 79*.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

GARY NICKOL
PRIMARY EXAMINER

Christopher Yaen
Art Unit 1642

ADVISORY ACTION

Claim Rejections Maintained - 35 USC § 102 & 103(a) – Jadus et al

1. Claims 31-33,35-37,40,49,52,62,64,67-70,72,74,78, and 79 remain rejected under 35 USC 102(a) and or 35 USC 103(a) as being either anticipated or obvious over Jadus *et al*. In a response filed 3/12/2004, applicant argues the rejections under 35 USC 102(a) and alternatively under 35 USC 103(a) as being not anticipated or not obvious over by Jadus *et al* . Under 102(a), applicant argues that the rejection does not meet the legal standards set forth in the MPEP because the reference of Jadus *et al* does not qualify as a 102(a) reference because the reference is a publication of a collaboration between the inventors and scientist from a research institution. Applicant further argues that the invention "by another" does not simply qualify as the sole means of determining the inventorship, but actually must rely on "who actually invented" the claimed invention, wherein the prior art can be rebutted by showing that the invention is the inventors own work. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. MPEP states that a "rejection can also be overcome by submission of a specific declaration by the applicant establishing that the article is describing applicant's own work." In re Katz, 687 F.2d 450, 215 USPQ 14 (CCPA 1982). Furthermore, it is also possible for the inventor to amend the inventorship to reflect the authorship of the published prior art (see MPEP 2132.01 In re Searles, 422 F.2d 431, 164 USPQ 623 (CCPA 1970). In the instant case, applicant has not furnished a declaration stating that the invention is the sole work of

the inventor, nor has the applicant provided an amendment to the inventorship to reflect the same authorship of the prior art.

Applicant also argues that the substance of the Jadus *et al* reference does not anticipate the instant invention because the reference only teaches the effects of M-CSF on tumor cells has on macrophage recognition, and that this does not anticipate the invention because the invention involves the administration of cytokine-expressing cells to a subject. This argument is not deemed persuasive because contrary to what applicant states, Jadus *et al* specifically teaches the administration of tumor cells transfected with M-CSF would be effective in generating an anti-tumor immune response (see page 5239), and therefore, a method of stimulating an anti-tumor immune response as claimed is still anticipated, because any composition that is intended for in vivo administration would also have pharmaceutical excipients. Therefore the rejection under 35 USC 102(a) is maintained.

Applicant also argues that the rejection under 103(a) cannot be maintained because the Jadus *et al* reference direct the reader away from the instantly claimed invention in that the reader is direct to inject into the tumor a retrovirus expressing the M-CSF – a form of gene therapy. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. Jadus *et al* alludes to the administration of tumor cells to a subject (see page 5239) and further states that M-CSF provides a means to target tumor cells to macrophages to stimulate an immune response (see page 5239, 1st col.). One of ordinary skill in the art would interpret such statements as a direct contemplation for the administration of tumor cells

expressing M-CSF as a means to direct said tumor cells to macrophages for the stimulation of an immune response. Such an immune response would be accomplished by the administration of a pharmaceutical composition comprising the cytokine expressing tumor cell with pharmaceutically acceptable excipients. Therefore the rejection under 35 USC 103(a) is maintained.

2. Because claims 34,38-39,41-48,50-51,63-66,71,73,75-77, and 80-81 were originally rejected under 35 USC 112, 1st or 2nd paragraph and because they are dependent on rejected base claim 31, these claims are now objected to for being dependent on rejected claims.

Christopher Yaen
Art Unit 1642
May 03, 2004

GARY NICKOL
PRIMARY EXAMINER